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March 16, 2001

Via Federal Express

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Our Ref.: 22963-1290

**Re: Draft U.S. Patent Application for
HELICALLY SHAPED ELECTROPHYSIOLOGY CATHETER
Inventors: Hill et al.**

Dear Dr. Chan:

Enclosed is a draft application for review by the inventors. Each of the inventors should carefully review the draft and provide us with their comments. In addition, each of the inventors need to write-in their residence address and citizenship where indicated on the *Notice to Inventors When Reviewing this Draft Application*.

We will finalize the application once we have received comments on the draft. Should you have questions, please call.

Sincerely,

Nita J. Miller
Patent Assistant

Enclosure

287093 v01.SV (655T01L.DOC)
3/16/01 10:56 AM (22963.1290)

Exhibit A

Heller Ehrman White & McAuliffe LLP 275 Middlefield Road Menlo Park, California 94025-3506 www.hewm.com

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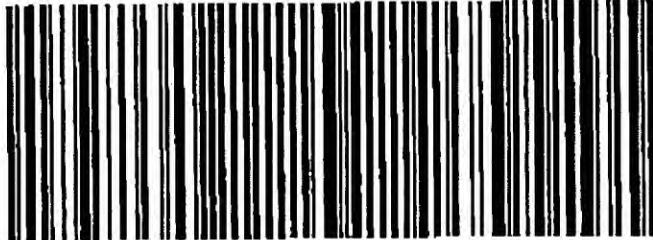
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NOTICE TO INVENTORS WHEN REVIEWING THIS DRAFT APPLICATION

READ the specification and claims and review the drawings carefully to ensure that they describe and illustrate your invention.

NOTE that if special processing, materials or designs have been developed or are needed to successfully make or use your invention, such special processing, materials or designs MUST be disclosed in your application.

NOTE that under U.S. patent law, you have an ongoing duty to disclose any references you are, or later become aware of which may be of interest to the Patent Examiner during the prosecution of your application. If you are unsure of the pertinence of a reference, please provide it to us for evaluation.

ALSO NOTE, that you have a duty to inform the Patent Office of the following activities if they occurred more than one year prior to the U.S. filing date:

- (1) any publication or written disclosure made by you to persons outside of Cardima, Inc., which was not subject to a confidentiality obligation with respect to the information;
- (2) any public use which was made of the invention; and
- (3) any sales activities offerings for sale of the invention.

PLEASE advise us of any references or activities that should be reported to the Patent Office upon filing of the application when the draft application is returned.

According to our records, the **INVENTORS** for this application are:

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Full Legal Name of Second and Joint Inventor: Alex L. Lim

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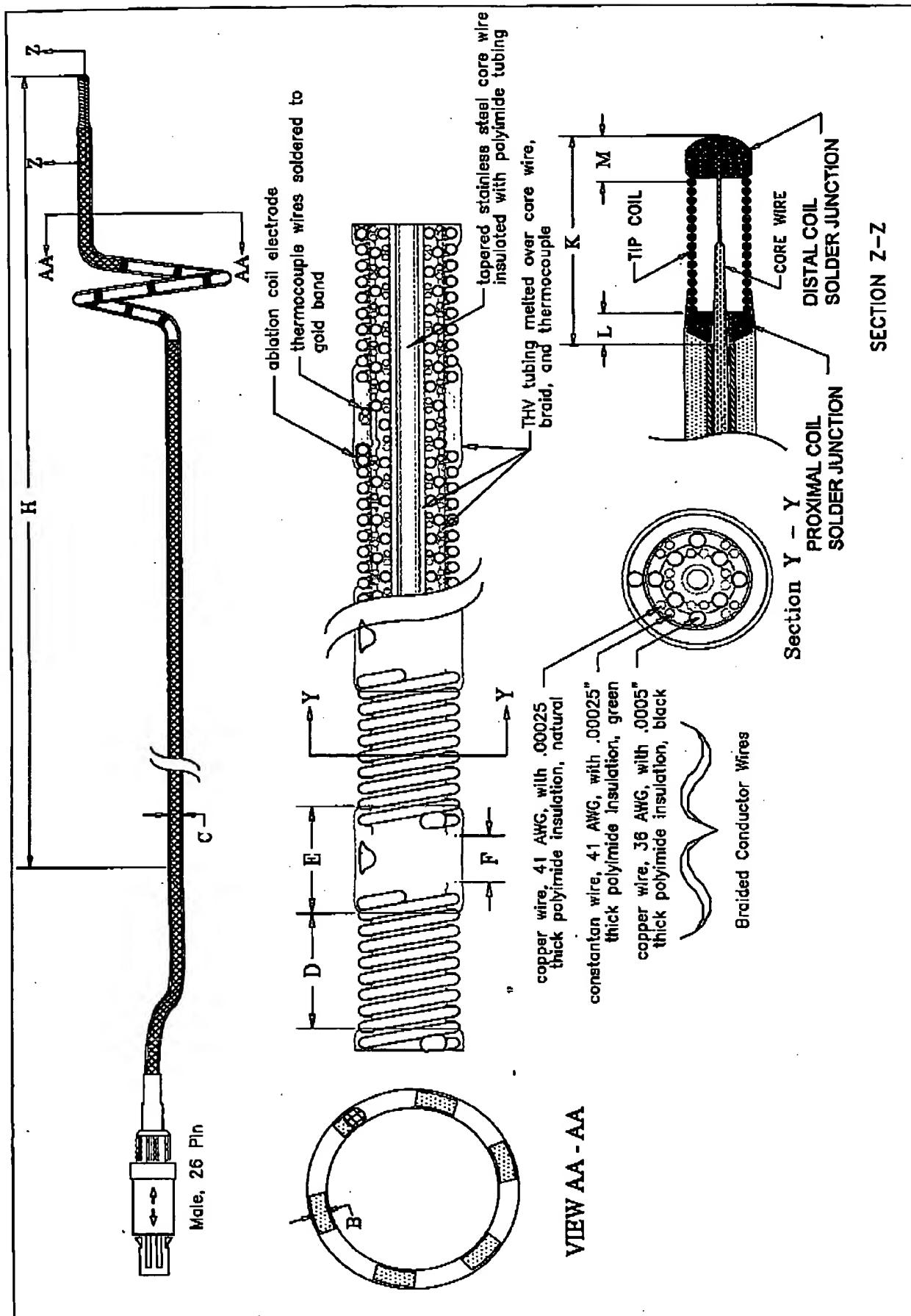
P.O. Box Address: (same as above)

Citizenship: _____

The final application will reflect only the person listed above as inventor. If you have any questions, please contact Priscilla Mark of Heller Ehman White & McAuliffe LLP at (650) 324-7184.

Title of Invention: **HELICALLY SHAPED ELECTROPHYSIOLOGY CATHETER**

Our Docket No. 22963-1290



Application of

Richard E. Hill, III.

Alex L. Lim

~~Gabriel B. Veach~~ Tim Huynh

and

Eric K. Y. Chan

for.

UNITED STATES LETTERS PATENT

on

HELICALLY SHAPED ELECTROPHYSIOLOGY CATHETER

Drawings: 6 Sheets
Docket No.: 22963-1290

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HELICALLY SHAPED ELECTROPHYSIOLOGY CATHETER**BACKGROUND OF THE INVENTION**

This invention generally relates to the treatment of cardiac arrhythmia and particularly atrial fibrillation and atrial flutter.

5 Atrial fibrillation is the disorganized depolarization of a patient's atrium with little or no effective atrial contraction. Prior methods for treating a patient's arrhythmia include the use of anti-arrhythmic drugs such as sodium and calcium channel blockers or drugs which reduce the Beta-adrenergic activity. Other methods include surgically sectioning the origin 10 of the signals causing the arrhythmia or the conducting pathway for such signals. However, the surgical technique is quite traumatic and is unacceptable to a large number of patients. A more frequently used technique to terminate the arrhythmia involves destroying the heart tissue which causes the arrhythmia by ablative energy, e.g., applying a laser 15 beam or high frequency electrical energy such as RF or microwave energy, to a desired arrhythmogenic site or pathway on the patient's endocardium. In the latter method, intravascular electrophysiological (EP) devices can be used to form lesions within a patient's atrial chamber to provide results similar to the surgical segregation techniques in terminating atrial 20 fibrillation, but with significantly reduced trauma.

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Typically, the EP device is advanced within a patient's vasculature and into a heart chamber, and a lesion is formed on the endocardium when RF electrical energy is emitted from electrodes of the device. RF ablation techniques produce lesions of a small area, so that several lesions are 5 typically formed to completely ablate an area. A major problem of RF ablation techniques is forming a lesion of the requisite size, which completely ablates the area of interest but does not unnecessarily destroy surrounding healthy tissue.

What has been needed is an ablation device which allows for 10 improved creation of lesions of a requisite shape. The present invention satisfies these and other needs.

SUMMARY OF THE INVENTION

This invention is directed to an electrophysiology (EP) device for ablating tissue within a patient's body lumen. The EP device of the 15 invention generally comprises an elongated shaft having a distal shaft section with a helical shape and at least one electrode on an exterior portion thereof. One aspect of the invention comprises a method of performing a medical procedure, such as treating a patient for atrial arrhythmia, by forming a lesion using an EP device embodying features of 20 the invention.

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In one embodiment, the helical shape of the distal shaft section is configured to conform to the inner diameter of a patient's body lumen, to form one or more lesions which extend around a wall defining the body lumen. Thus, the turns of the helical distal shaft section have an outer diameter which is not significantly smaller or significantly larger than the inner diameter of the body lumen at the desired site of the lesion. In a presently preferred embodiment, the diameter of the turns is substantially equal to the inner diameter of the body lumen, so that the turns contact the wall defining the body lumen without significantly expanding and injuring the body lumen wall.

In another embodiment, the distal shaft section has a proximal portion with a helical shape and a distal portion with a noncoiled shape. The noncoiled distal portion, which thus is not wound into circular or spiraled configuration, in one presently preferred embodiment has a substantially straight shape. The terminology "substantially straight" should be understood to mean a portion configured to extend in a line, although some minor variations in the shape of the portion may be present. In a presently preferred embodiment, sensing electrodes are provided on the noncoiled distal portion of the distal shaft section. The sensing electrodes can be used to map electrical activity in the region of the electrodes, or to

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pace the electrical activity of a region of the patient's anatomy such as the patient's heart.

In a presently preferred embodiment, the EP device has a core member extending within the elongated shaft. The core member preferably has a helically shaped distal section to provide the helical shape to the distal shaft section of the EP catheter. The core member may be fixed within the shaft, or alternatively, slidably disposed therein. In the embodiment in which the core member is slidably disposed within the shaft, a variety of different core members may be provided allowing the physician to choose a core member comprising a particularly suitable size, shape or material. Thus, an EP device with a distal shaft section having a desired shape is provided by inserting a core member having the desired shape therein. The core member may be provided with one or more jackets, which may be electrically insulating, having a total thickness of preferably less than about 0.001 inch (0.025 mm).

The distal shaft section of the EP device is preferably reversibly deformable from the helically shaped configuration to a lower profile configuration for advancement within the patient's vasculature. In one embodiment, the EP device of the invention is slidably disposed in the lumen of a guiding catheter, so that the radial force of the guiding catheter

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against the device reversibly collapses the turns of the helically shaped distal section to smaller diameter turns which fit within the guiding catheter. In another embodiment, the turns of the helically shaped distal section are configured to reversibly collapse completely, so that the guiding catheter straightens the helically shaped distal section to a straight configuration.

5 The EP device distal shaft section is thus constrained from assuming the expanded helical configuration until the device is displaced out a distal end of the guiding catheter.

The one or more ablation electrodes on the helically shaped distal shaft section form a lesion from within a patient's body lumen when electrical energy, and preferably high frequency energy such as RF energy, is emitted therefrom. The ablation electrode(s) on the helically shaped distal shaft section may be a combination ablation and sensing electrode, which is capable of ablation and detection of electrical activity from within a lumen of the patient's body. In a presently preferred embodiment, the ablation electrode on the helically shaped distal shaft section is a helical coil for improved device flexibility, although other electrode designs are suitable including cylindrical bands, arcuate bands, ribbons or the like. A temperature sensor such as a thermocouple may be provided on the EP device. In one embodiment, one or more sensing electrodes for mapping

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and/or pacing are provided on the shaft proximal and/or distal to the helically shaped section. Preferably, the ~~ablation electrodes on the~~ ~~ablation electrodes on the~~ ~~helically shaped distal shaft section are configured for unipolar use during ablation,~~ ~~helically shaped distal shaft section and the sensing electrodes are~~ ~~and bipolar use during sensing, by using a multiplexing switch box. The ablation~~ ~~configured for bipolar use (Question: is this correct?). Alternatively,~~

5 ~~distal to the helical segment uni~~ electrodes on the EP device shaft ~~may be~~ ~~configured for unipolar use or~~ ~~for pacing and sensing. In the unipolar pacing/sensing mode,~~ ~~with~~ ~~a separate, return electrode which is not on the EP device shaft but~~

external ~~An~~ ~~return~~ which is in contact with the exterior surface of the patient's body is used. ~~electrode in contact " " " " " " " " is also used in~~

10 In a method of the invention, the helically shaped distal shaft section of the EP device is placed at an ostium or within a body lumen at a desired location. The terminology "body lumen" should be understood to include a variety of structures in the body, including a blood vessel and a heart chamber. Typically, an EP device assembly comprising the EP device of the invention within a guiding catheter is advanced within a patient's body lumen to a desired location therein. The EP device distal shaft section is then deformed from the low profile configuration to the helical configuration by displacing the EP device relative to the guiding catheter so that the distal shaft section of the device extends at least in part outside of the guiding catheter lumen in the body lumen. The helically shaped distal shaft section of the device contacts a wall defining the body lumen or ostium.

15 The electrodes are then used to detect electrical activity from within the

the unipolar ablation mode.

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body lumen to determine the desired site for forming a lesion. One or more of the electrodes on the helically shaped distal shaft section contact the wall defining the ostium or the inner surface of the body lumen, so that delivery of high frequency energy to the electrodes forms a lesion 5 extending in whole or in part, one or more times, around the ostium or the inner surface of the body lumen. The lesion may be a helically shaped lesion extending spirally along a length of the body lumen, or may be one or more circular lesions. The helical shape of the distal shaft section is configured to provide lesions particularly suitable for treatment of atrial 10 arrhythmia including atrial fibrillation or flutter. In one embodiment, a plurality of discontinuous lesions are formed, which thus limits or avoids the possible disadvantageous results, such as stenosis formation and spasms in the ablated region, which otherwise occur from a continuous lesion extending around the full circumference of the ostium or body lumen.

15 The EP device of the invention has a helically shaped distal section, which allows for the formation of lesions extending in whole or in part around the inner surface of a patient's body lumen. The helically shaped distal section provides improved lesion formation within a body lumen due to the helical turns configured to conform to the body lumen inner diameter.

20 The turns of the helically shaped distal shaft section can be moved closer

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together or further apart within the patient to provide the desired lesion pattern. Additionally, the device has a low profile configuration for advancement within the patient which self expands into the helically shaped configuration for easy of deployment within the patient. These and 5 other advantages of the invention will become more apparent from the following detailed description and the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is an elevational view of an EP device embodying features of the invention, having a helically shaped distal shaft section.

10 Fig. 2 is a transverse cross-sectional view of the EP device shown in Fig. 1, taken along the lines 2-2.

Fig. 3 is an elevational view, partially in section, of an EP device assembly embodying features of the invention, illustrating an EP device in a low profile configuration within a guiding catheter.

15 Fig. 4 is an enlarged longitudinal cross-sectional view of the EP device assembly shown in Fig. 3 taken along the lines 4-4, illustrating the EP device distal tip within the guiding catheter.

20 Fig. 5 is an enlarged longitudinal cross-sectional view of the EP device assembly shown in Fig. 3 taken along the lines 5-5, illustrating a portion of the EP device distal shaft section within the guiding catheter.

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Fig. 6 is a transverse cross sectional view of the EP device assembly shown in Fig. 5, taken along lines 6-6.

Fig. 7 is a transverse cross sectional view of an alternative embodiment of an EP device assembly embodying features of the 5 invention, having a core wire slidably disposed in a lumen in the device shaft.

Fig. 8 is an elevational view, partially in section, of a patient's heart and an EP device assembly embodying features of the invention, with the distal end of the EP device transeptally positioned within a pulmonary vein.

10 Fig. 9 is an elevational view, partially in section, of the EP device assembly of Fig. 8, with the turns of the helically shaped distal shaft section moved closer together in a stacked configuration.

15 Fig. 10 is an elevational view of an alternative embodiment of an EP device embodying features of the invention comprising a distal shaft section having a proximal portion with a helical shape and a distal portion with a noncoiled shape.

Fig. 11 is a longitudinal cross sectional view of the distal end of the EP device of Fig. 10, taken within circle 11.

20 Fig. 12 is an elevational view, partially in section, of the EP device of Fig. 10, positioned in contact with a wall defining a pulmonary vein ostium,

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with the turns of the helically shaped distal shaft section moved closer together in a stacked configuration.

DETAILED DESCRIPTION OF THE INVENTION

Fig. 1 illustrates one embodiment of the EP device 10 of the invention, generally comprising an elongated shaft 11 having a proximal shaft section 12, a helically shaped distal shaft section 13, and a plurality of electrodes 14 on the distal shaft section 13. An electrical connector 15 and an adapter 16 are on the proximal end of the device (Question: Is the illustration of the proximal end adapter/connector correct in Fig. 1?).

Fig. 2 illustrates a transverse cross section of the distal end of the device 10 shown in Fig. 1, taken along lines 2-2.

10

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) Good enough
See new
drawing
enclosed.

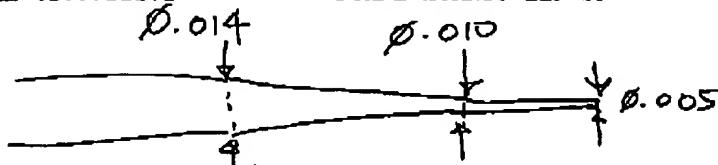
Fig. 3 illustrates the EP device 10 within a guiding catheter 20 for introduction and advancement within the patient. The guiding catheter generally comprises an elongated shaft 21 having a proximal end 22, a distal end 23, a port 24 in a proximal shaft section, a port 25 in a distal shaft section, and a lumen 26 extending within the shaft to the port in the distal shaft section. As illustrated in Fig. 3, the helically shaped distal shaft section of the EP device 10 is reversibly deformed from the helical configuration to a low profile configuration within the lumen 26 of the guiding catheter. In the embodiment illustrated in Fig. 3, with the EP device

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slidably disposed within guiding catheter lumen 26, the radial force of the guiding catheter 20 against the device reversibly straightens the helically shaped distal section to form a straight configuration. The helically shaped distal shaft section 13 is preferably self expanding, so that the EP device 5 10 can be advanced out the distal end of the guiding catheter 20, or the guiding catheter 20 proximally retracted, causing the distal shaft section of the EP device to return to the helically shaped configuration illustrated in Fig. 1. In alternative embodiments (not shown), the helically shaped distal shaft section reversibly collapses to a helical shape with turns having a smaller outer diameter when the distal shaft section is within the guiding 10 catheter lumen 26.

In a presently preferred embodiment, the EP device 10 includes a core member 17 having a helically shaped distal section, disposed within the shaft 11. As best illustrated in Fig. 5, showing a longitudinal cross section of the EP device shown in Fig. 3, taken along lines 5-5, the shaft 11 comprises a tubular member 18 disposed about the core member 17. The core member 17 extends within the tubular member to the distal end of the device, and the tubular member 18 is helically shaped by the core member therein. Fig. 6 illustrates a transverse cross section of the EP 15 20 device shown in Fig. 5, taken along lines 6-6.

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The core member 17 is preferably formed of a superelastic material, such as a NiTi alloy, or stainless steel, and has a maximum diameter of about 0.01 inch (.25 mm) to about 0.018 inch (.46 mm). The core member 17, and preferably a distal section thereof, may be tapered as shown in Fig. 4, or optionally flattened. In a presently preferred embodiment, the core member has an insulating coating 30, such as a polyester or polyimide coating. The coating 30 is preferably about 0.001 inch (0.025 mm) thick. In the embodiment illustrated in Fig. 4, coating 30 extends distally to a point distal to the shaft 11 distal end and proximal to the distal end of core member 17. In the embodiment illustrated in Figs. 5 and 6, the coating 30 on the core member 17 contacts an inner surface of the tubular member 18. The core member 17 is secured to the tubular member 18 by applying heat to the device to melt and fuse the tubular member to the core member coating. However, a variety of suitable means of securing the core member within the tubular member may be used, such as an adhesive (not shown) between the core member and the tubular member. In an alternative embodiment of the invention illustrated in Fig. 7, the core member 17 is slidably disposed within and removable from a lumen 19 of the tubular member.

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As best illustrated in Fig. 4, a flexible coiled tip 27 is provided on the distal end of the EP device 10. The tip 27 has a closed distal end, and includes a flexible coil 28 extending beyond the distal end of the shaft 11 enclosed within a soft coating 29 preferably formed of a polymeric material.

5 In the embodiment illustrated in Fig. 4, the tip 27 has an open center region for increased flexibility. A presently preferred polymeric material for the tip 27 is a fluoropolymer such as THV available from 3M. In the embodiment illustrated in Fig. 4, the core member 17 is secured to the distal end of the coil 28, by suitable material such as gold-tin solder. In
10 another embodiment of the invention, the coil 28 may be omitted, and the distal end of the EP device preferably provided with a soft tip to minimize traumatic engagement with a blood vessel wall.

In the embodiment illustrated in Figs. 5 and 6, the electrodes 14 comprise helical coils which are electrically connected to insulated
15 electrical conductors 31. In a presently preferred embodiment, the EP device 10 shaft includes thermocouples 32, connected to temperature sensor electrical conductors 33 and 34 (i.e., thermocouple wires). Thermocouples are preferably located between adjacent electrodes on an outer surface of the shaft 11, although they may alternatively be at other
20 locations on the EP device as is conventionally known. A conducting

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member 35, such as a gold band, covers the thermocouples, and a polymeric jacket 36, preferably formed from THV, covers the conducting member 35 and insulates the thermocouple 32 from noise (e.g. RF noise) present as a result of the energy sent to the electrodes. In the embodiment 5 illustrated in Fig. 5, the electrical conductors 31 and thermocouple wires 33, 34 are braided within the tubular member 18. In an alternative embodiment (not shown), the individually insulated electrical conductors may be within the tubular member lumen 19 or at least in part within an outer jacket of the core member in the embodiment in which the core 10 member is secured to the tubular member. The proximal ends of the electrical conductors 31 and thermocouple wires 33, 34 are electrically connected to individual pins of multi-pin connector 15 (Fig. 1) on the proximal end of the shaft.

In a method of treating a patient for atrial fibrillation or flutter, the EP 15 device of the invention is used to form a lesion extending around an inner surface of the patient's pulmonary vein. Fig. 8 illustrates an assembly in a patient's heart 40, with the EP device 10 in a pulmonary vein 41. The device 10 is introduced into the patient's vascular system, e.g. the femoral vein, percutaneously or by way of a cut-down, within the guiding catheter 20. The assembly is preferably advanced into the right atrium 42 from the

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inferior vena cava 43, and positioned in the left atrium 44 transeptally, as illustrated in Fig. 8. The EP device 10 distal section extends out of the port in the distal end of the guiding catheter, so that the helically shaped distal shaft section of the device is positioned within the pulmonary vein 41 of the heart. The pulmonary vein 41 is mapped using electrodes on the device 10, and if a pulmonary vein potential is detected, the electrodes on the distal shaft section are used to form a lesion(s) extending at least in part *or in the left atrium just outside a pulmonary vein or* around the wall defining the pulmonary vein lumen, *A*. The position of the lesion is preferably chosen to interrupt the conduction path to the atrium. Alternatively, the lesion may be located to ablate the actual focal origin in the pulmonary vein.

Typically, RF current is delivered to one or two electrodes to perform a first ablation and then to adjacent electrodes, one or two electrodes at a time, until an ablation of desired length is obtained in the body lumen. This reduces the overall power requirements for the assembly. The temperature sensors can be used to detect the temperature of the heart wall between the adjacent electrodes, to control the high frequency energy and determine when the lesions formed by adjacent electrodes overlap to form continuous lesions on the wall defining the body lumen. Additionally, feedback of the temperature data can be used to modulate the power and

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prevent thrombus in the preferred use, and cooling fluid can also be used. After the ablation, the electrodes 14 can be employed to detect electrical activity to ensure that the ablation has been effective in terminating the fibrillation or flutter. Typically, the procedure is performed for the left and

5 right, superior and inferior pulmonary veins.

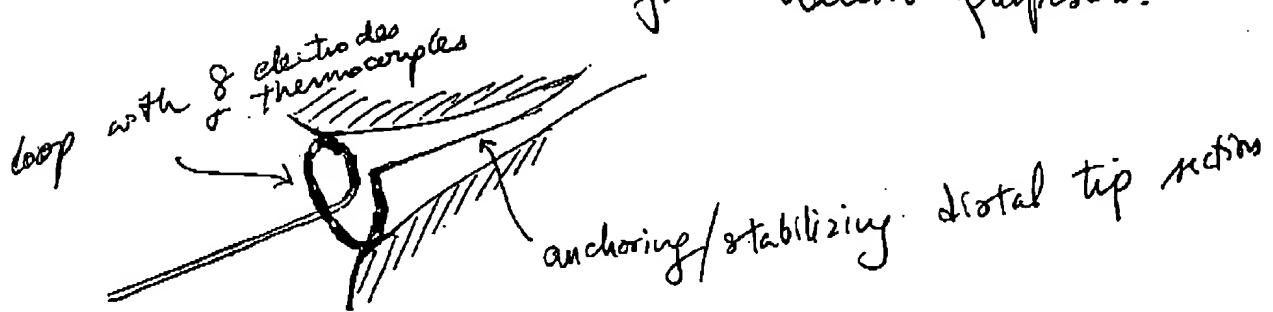
The EP device of the invention can be used to form either a helical or a curvilinear segmental lesion, lesion or a closed circular lesion. For example, in the embodiment illustrated in Fig. 8, a helical lesion on the body lumen wall can be formed by delivering RF energy to the electrodes which as illustrated are 10 contacting the pulmonary vein wall in a helical array. Typically, the helical lesion is formed to extend continuously along the body lumen wall, wherein the individual lesions formed by the longitudinally adjacent electrodes on the shaft overlap to produce one continuous lesion. The helical lesion comprises a spiral having a distal end, and a proximal end longitudinally 15 spaced from the distal end of the spiral. In an alternative embodiment of the invention, the lesion formed extends in a closed circle around the body lumen wall, i.e., a lesion having ends that close together to form a circle. A closed circle lesion can be formed by displacing the device distal section to change the electrode position on the body lumen wall after an initial lesion 20 is formed. For example, in one embodiment of the method of forming a

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Note 1

Add to p. 17 overleaf.

In yet another embodiment, the helical loop portion could be placed just outside a pulmonary vein OS, and the distal section used as an anchoring section. The loop could be pushed against the atrial tissue just outside the PV OS, thereby ensuring good contact with atrial tissue for ablation purposes.



The electrodes are used to map for pulmonary vein potentials and only a segmental rather than an entire circumferential lesion is formed by RF ablation, to barricade the p.v. potentials from exiting the P.V.

closed circular lesion, a helically shaped lesion is first formed on the body lumen wall, and then the helically shaped distal shaft section of the EP device is rotated or longitudinally displaced proximally or distally, and a second lesion which overlaps with the first lesion is formed, to thereby form 5 at least one closed circular lesion. Alternatively, as illustrated in Fig. 9, the helically shaped distal shaft section of the EP device can be provided with closely spaced, stacked adjacent turns which facilitate the formation of a closed circle lesion. → ~~see enclosed!~~ (attached)

10 The spacing between adjacent turns of the helically shaped distal shaft section can be changed by the physician during deployment of the EP device within the body lumen. To increase the spacing between the helical turns of the device, the distal extremity of the EP device is displaced out of the distal end of the guiding catheter so that it is placed in contact with the body lumen wall. The guiding catheter is displaced proximally, while a 15 proximal portion of the EP device is displaced proximally to stretch the turns of the helically shaped distal shaft section apart, so that the portion of the EP device distal shaft section that is still inside the guiding catheter is deployed therefrom with the spacing between the turns increased. Similarly the spacing between the turns may be decreased by retracting the 20 guiding catheter proximally while a proximal portion of the device is

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displaced distally, to stack the turns of the helically shaped distal shaft section together.

Fig. 10 illustrates an alternative embodiment of an EP device 110 which embodies features of the invention, generally comprising an 5 elongated shaft 111 having a proximal shaft section 112, a distal shaft section 113, and a plurality of electrodes 114 on the distal shaft section 113. An electrical connector 115 is on the proximal end of the device 110. The distal shaft section 113 comprises a proximal portion 116 with a helical shape having one or more turns, and a distal portion 117 extending from 10 the proximal portion with a noncoiled shape. In the embodiment illustrated in Fig. 10, the noncoiled distal portion 117 has a straight shape with an outer surface aligned or parallel with an outer surface of the proximal shaft section 112. The electrodes 114 on the helically shaped proximal portion preferably comprise coiled electrodes, and temperature sensors 118 are 15 located between the coiled electrodes 114, preferably on an outer surface of the shaft, as discussed above in relation to the embodiment of Fig. 1. In a presently preferred embodiment, each electrode 114 has a length of about 3 to about 6 mm. Although 5 electrodes 114 are illustrated in Fig. 20, the number of electrodes 114 may vary, and in a presently preferred embodiment, about 8 electrodes are provided on EP device 110. A pair of

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sensing electrodes 119 for mapping and/or pacing are on the distal portion 117 of the distal shaft section. In an alternative embodiment (not shown) at least a second pair of sensing electrodes 119 may be provided on the shaft proximal to the helically shaped proximal portion 116. The sensing electrodes are preferably spaced away from the helically coiled section 116, and in one embodiment are about 1 to about 3 cm, preferably about 5 1.5 to about 2 cm from the helically coiled section. In a presently preferred embodiment, the ablation electrodes 114 and the sensing electrodes 119 are bipolar electrodes (Question: Is this correct?). A flexible coiled tip 10 120 is secured to the distal end of the distal portion 117, to facilitate guiding the EP device to a desired location within the patient. In a presently preferred embodiment, the tip coil 120 is about 1 to about 3 cm, most preferably about 2 cm in length, and is formed of a radiopaque metal such as platinum.

15 The turns of the helical proximal section 116 are illustrated in a relaxed configuration in Fig. 10. However, the turns of the helical proximal section 116 can be moved closer together or further apart within the patient by urging the proximal end of the catheter distally or proximally, respectively, with the distal end of the catheter in a stabilized position

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within the patient and as discussed above in relation to the embodiment of Fig. 1.

Each electrode 114 is spaced apart from one or more adjacent electrodes 114 on the shaft 111, i.e., the electrodes 114 extend discontinuously along the shaft. However, depending on the duration and power level used during an ablation procedure, the lesion(s) formed by electrodes 114 can be discontinuous or alternatively, can be joined together and thus continuous.

In the embodiment illustrated in Fig. 10, the helical proximal portion 116 forms one full 360° loop and ~~and half of a second loop~~. In a presently preferred embodiment, about ~~2 to about one~~ full 360° loops are provided, although the number of loops may vary. Because the proximal portion 116 is helical, a proximal section of the 360° loop is longitudinally spaced apart from the distal section thereof which completes the circumference of the loop in the relaxed configuration illustrated in Fig. 10. Consequently, the helical proximal portion forms at least one open or helical 360° loop in the relaxed configuration, and the electrodes 114 thereon form an open or helical 360°, discontinuous loop. The circumference of one 360° loop of the helically proximal portion 116 varies depending on the desired use of the EP device. In a presently preferred

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15 embodiment, the circumference of one 360° loop is about 45 mm to about
480 mm, preferably about 47 mm to about 78 mm. Depending on the
15 circumference of the loop and the number and length of the electrodes 114,
the electrodes 114 may or may not extend the length of one or more 360°
5 loops. In a presently preferred embodiment, the electrodes 114 extend
along the length of at least one 360° loop of the helical proximal portion
116, so that the electrodes can be used to form a lesion which extends in a
continuous, or discontinuous, 360° loop (Question: is this correct).
However, in alternative embodiments, the helical proximal portion 116 has
10 a partial loop of less than 360° (not shown), or the electrode number or
length is sufficiently small such that the electrodes extend along a length of
a partial loop of less than 360° on the helical proximal portion.

Fig. 11 illustrates an enlarged, longitudinal cross sectional view of
the distal end of the device 110, taken within circle 11. As illustrated in Fig.
15 11, the shaft 111 comprises a tubular member 121, having braided
electrical conductors 122 in the wall of the tubular member 121, and having
a core member 123 in a lumen of the tubular member 121. In the
embodiment illustrated in Fig. 11, the core member 123 is secured to the
flexible coiled tip 120. An outer layer 124 on an outer surface of the tubular
20 member 121 overlaps the ends of the sensing electrodes 119.

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Fig. 12 illustrates the device 110 with the helically coiled proximal portion 116 of the distal shaft section 113 in position at the ostium 46 of a pulmonary artery which forms the junction between the pulmonary artery and the right atrium of the patient's heart. As illustrated in Fig. 12, the turns 5 of the helically shaped proximal portion 116 are in a stacked configuration after having been moved closer together than the natural relaxed spacing shown in Fig. 10, by distally forcing the catheter against the wall defining the ostium of the pulmonary artery. As a result, the electrodes 114 extend discontinuously, completely around the ostium. High frequency energy is 10 delivered to one or more of the electrodes 114 to form a lesion extending at least in part around the ostium. The lesion can be caused to be a continuous or a discontinuous circular lesion depending on the energy level and the length of time of the ablation, and by rotating the catheter one or more times between delivery of ablation energy to electrodes 114. As 15 illustrated in Fig. 12, the distal portion 117 of the distal shaft section is positioned within the pulmonary vein 41, to allow for mapping and/or pacing from within the pulmonary vein. Thus, the sensing electrodes allow for sensing electrical activity before and after the ablation energy is delivered to electrodes 114, to determine the appropriate location of the device, and 20 whether the lesions formed therefrom sufficiently treated the atrial

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arrhythmia. Although not illustrated, in one embodiment of performing a medical procedure, the helically shaped proximal portion 116, and the distal portion 117 of the EP device 110 are both positioned within the pulmonary vein 41, similar to the embodiment illustrated in Figs. 8 and 9.

5 In a presently preferred method of the invention, the lesion

curvilinear comprises _____ (Question: is it (a) or (b): (a) one or
lesions

more ~~closed circles~~ on the endocardium. [^] b) ~~a helical lesion(s)~~ that may be a partial or full
~~extending along a length of the endocardium~~. Typically, the lesion ^{circle.}

formed with the EP device 10/110 of the present invention has a width of

10 about 2 to about 7 mm, preferably about 3 to about
4 mm. A helical lesion extending along a ^{curvilinear} length of the body lumen ^{circumferentially (partial or full)}
^{segment}

has a length of about 5 to about 35 mm, preferably about 5

to about 20 mm. Preferably, in the embodiment in which a plurality of

closed circle lesions are formed on the body lumen wall, the lesions are

15 formed along a length of about _____ to about _____ mm, and preferably
near the transition zone between left atrial tissue and pulmonary vein tissue.
to about _____ mm of the body lumen wall.

The EP device 10/110 has a total length, including the connector 16,

of about 100 cm to about 200 cm, and preferably between 150 and 180,

e.g. about 165 cm. The length of the distal shaft section 13/113 having

20 electrodes 14/114 is about 2 cm to about 15 cm, and preferably about 4 to

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about 8 cm, e.g. about 6 cm. The outer diameter of the distal shaft section of the device is typically about 1.0 mm (3.0 French) to about 2.0 mm (6.0 French), and preferably about 1.3 mm (4 French) to about 1.7 mm (5 French). The maximum outer dimensions of the electrodes are generally 5 about 1.0 mm (3 Fr) to about 1.3 mm (4 Fr), and preferably about 1.22 mm (3.7 Fr). The electrode length is about 2 mm to about 8 mm, and preferably about 4 to about 7 mm, e.g. about 6 mm. The interelectrode spacing is generally about 1 mm to about 3 mm, and preferably about 2 mm. In a presently preferred embodiment, the interelectrode spacing is 10 uniform. However, the electrode spacing may alternatively be nonuniform. In a presently preferred embodiment, about 4 to about 12 individual electrodes are provided on the shaft distal section, however, the device may have larger number of electrodes if the diameter of the distal section is increased to greater than 5 Fr.

15 Typically, the device is used within the patient's vasculature, although it may also be used to create lesions within other body lumens. The device may be advanced retrogradely through the aorta and left ventricle via a femoral artery access site. As illustrated in Fig. 8, the guiding catheter may have a bent or deflectable distal end. Torquing the 20 proximal section 22 of the guiding catheter, which extends out of the

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patient during the procedure, will cause the distal section thereof to be rotatably displaced within the body lumen and allow the EP device 10 to be properly positioned.

To the extent not already discussed herein, the EP device
5 components can be formed of conventional materials. The core member 17/123 can be formed of a variety of suitable materials including high spring-back metals, or superelastic metals, or shape memory metals, such as ELGILOY available from Carpenter Technology of Pennsylvania, MP35N, available from SPS Technologies, high tensile strength steel
10 including 304 vacuum-melted steel, and titanium alloys including Ti-GAI-4V, C_p Titanium, and NiTi.

The electrical connector 14 on the proximal end of the device may be a commercially available electrical connector such as Part No. PAB-M08-GLA39J or PAB-M08-TLA39J for an eight pin connector or Part No. PAB-15 M08-GLA39A for a connector with a greater number of pins, e.g. 9-16. The above connectors are available from Lemo USA, Inc. in Santa Rosa, CA. Suitable connectors for accessory cables connectable to the above connectors include PRB-M08-GLL65J for eight pin connectors and PRB-M08-GLL65A for connectors with more than eight pins. The latter
20 connectors are also available from the same source.

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While the invention has been described herein in terms of certain preferred embodiments directed to the detection and treatment of atrial fibrillation and flutter, those skilled in the art will recognize that the invention may be employed in a wide variety of procedures. A variety of 5 modifications and improvements may be made to the present invention without departing from the scope thereof. Moreover, although individual features of embodiments of the invention may be shown or discussed in relation to some of the embodiments and not in others, those skilled in the art will recognize that individual features of one embodiment of the 10 invention can be combined with any or all the features of another embodiment.

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WHAT IS CLAIMED IS:

1. An electrophysiology device for use in a patient's body lumen, comprising:

5 a) an elongated shaft having a proximal end, a distal end, and a distal shaft section with a helical shape having one or more turns configured to conform to an inner diameter of the body lumen; and

b) at least one electrode on an exterior portion of the distal shaft section.

10 2. The device of claim 1 wherein the turns of the helically shaped distal shaft section have a diameter substantially equal to a diameter of the body lumen.

*The preferred embodiment? (at least one turn?)
has $\approx \frac{1}{4}$ turn* [^] 3. The device of claim 1 wherein the helically shaped distal shaft section has a plurality of turns having substantially equal diameters.

15 4. The device of claim 1 wherein the shaft comprises a tubular member disposed about a core member.

5. The device of claim 4 wherein the core member has distal section having a helical shape.

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6. The device of claim 4 wherein the core member comprises a NiTi alloy.

7. The device of claim 4 wherein the shaft has a lumen extending therein configured to slidably receive the core member.

5 8. The device of claim 1 including a plurality of sensing and ablation electrodes on the distal shaft section.

9. The device of claim 1 wherein the distal shaft section includes a proximal portion having the helical shape, and a distal portion extending from the proximal portion with a noncoiled shape.

10 10. The device of claim 9 wherein the distal portion has a substantially straight shape.

11. The device of claim 9 including a flexible coiled tip extending from the distal end of the proximal portion.

12. An electrophysiology device, comprising:

15 a) an elongated shaft having a proximal end, a distal end, and a distal shaft section having a proximal portion with a helical shape having one or more turns, and a noncoiled distal portion; and

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b) at least one electrode on an exterior portion of the distal shaft section.

13. The device of claim 12 wherein the distal portion has a substantially straight shape.

5 14. The device of claim 12 wherein the at least one electrode is on the helical proximal portion.

15. The device of claim 12 including at least one electrode on the distal portion.

16. The device of claim 12 having a plurality of ablation electrodes 10 on the helical proximal portion, and at least two sensing electrodes on the distal portion.

17. The device of claim 16 including at least two sensing and *pacing* electrodes on a proximal section of the shaft located proximal to the helical proximal portion.

15 18. The device of claim 12 including a flexible coiled tip extending from a distal end of the distal portion.

19. The device of claim 12 wherein the distal portion has a length of about 20 to about 80 mm.

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20. The device of claim 12 wherein the helical proximal portion has a length of about 15 to about 40 mm.

circumference (outer O.D. of loop)

21. A method of performing a medical procedure, comprising:

- a) providing an electrophysiology device, comprising
 - an elongated shaft having a proximal end, a distal end, and a distal shaft section having a proximal portion with a helical shape having one or more turns and a distal portion with a noncoiled shape; and
 - at least one electrode on an exterior portion of the helical proximal portion; and

- b) positioning at least a section of the helical proximal portion in contact with a wall defining an ostium of a patient's body lumen; and

- c) delivering high frequency energy to the electrodes to form a lesion.

15
22. The method of claim 21 including after (b), moving the turns of the helical proximal portion closer together by distally forcing the catheter against the wall defining the ostium.

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23. The method of claim 21 wherein the ostium is a junction of a pulmonary vein with a left atrium, and (c) comprises forming a plurality of discontinuous lesions around the ostium.

24. The method of claim 21 wherein the ostium is a junction of a 5 pulmonary vein with a left atrium, and the device has at least one sensing electrode on the distal portion, and including mapping the pulmonary vein by sensing electrical activity with the sensing electrode.

25. A method of performing a medical procedure, comprising:

- a) providing an electrophysiology device, comprising
 - i) an elongated shaft having a proximal end, a distal end, and a distal shaft section with a helical shape having one or more turns configured to conform to an inner diameter of a body lumen of the patient; and
 - ii) at least one electrode on an exterior portion of the distal shaft section;
- b) positioning the device within the body lumen, so that the electrodes contact a wall defining the body lumen; and
- c) delivering high frequency energy to the electrodes on the device to form a lesion extending at least in part around the wall defining the body lumen.

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26. The method of claim 25 wherein the medical procedure is treating a patient for atrial arrhythmia, and (b) comprises positioning the device in a pulmonary vein.

27. The method of claim 26 wherein the device has a plurality of 5 electrodes on the helical distal shaft section, and including forming a plurality of discontinuous lesions extending in a helical pattern along a ^{or circular or curvilinear} _A length of the pulmonary vein.

28. The method of claim 26 wherein the device has a plurality of electrodes on the helical distal shaft section, and including forming a 10 plurality of lesions connected together to form a continuous lesion extending in a helical pattern along a length of the pulmonary vein.

29. The method of claim 25 wherein the device has a plurality of electrodes on the helical distal shaft section, and including after (c), moving the turns of the helical distal shaft section closer together and delivering 15 high frequency energy to at least one electrode on the helical distal shaft section to form a second lesion continuous with the first lesion.

30. The method of claim 26 wherein the device distal shaft section includes a proximal portion with the helical shape having a plurality of ablation electrodes, and a distal portion extending from the proximal portion

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with a noncoiled shape having at least one sensing electrode, and
including and including mapping the pulmonary vein by sensing electrical
activity with the sensing electrode, or, ^{delivering} pacing stimuli with this
single electrode.

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ABSTRACT OF THE DISCLOSURE

An electrophysiology (EP) device suitable for ablating tissue within a patient's body lumen. The EP device of the invention generally comprises an elongated shaft having a distal shaft section with a helical shape and at least one electrode on an exterior portion thereof. One aspect of the invention comprises a method of performing a medical procedure, such as treating a patient for atrial arrhythmia, by forming a lesion using an EP device embodying features of the invention.

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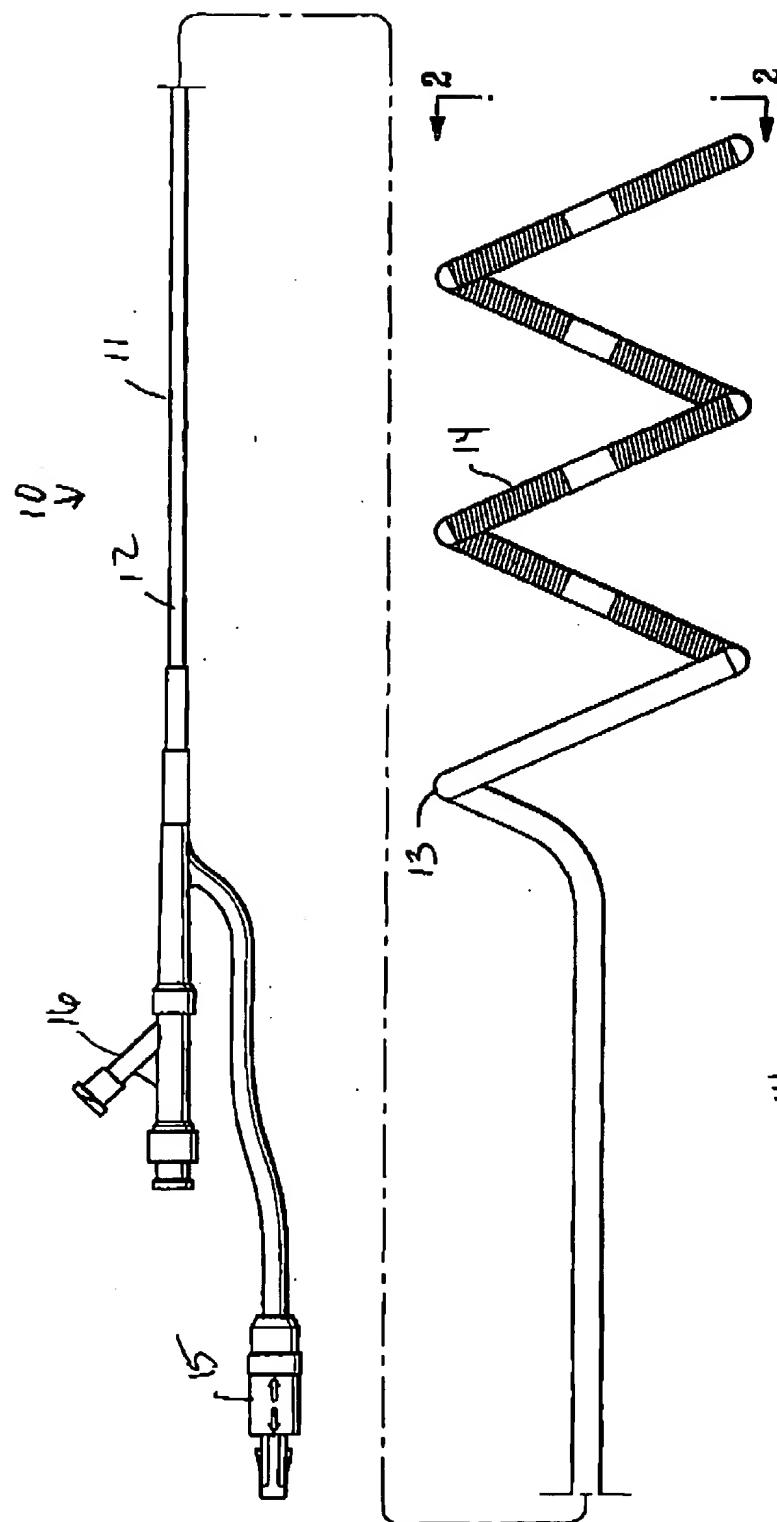
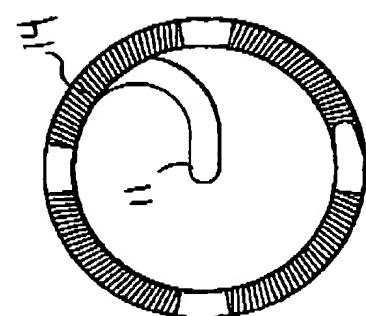


FIG. 1

FIG. 2

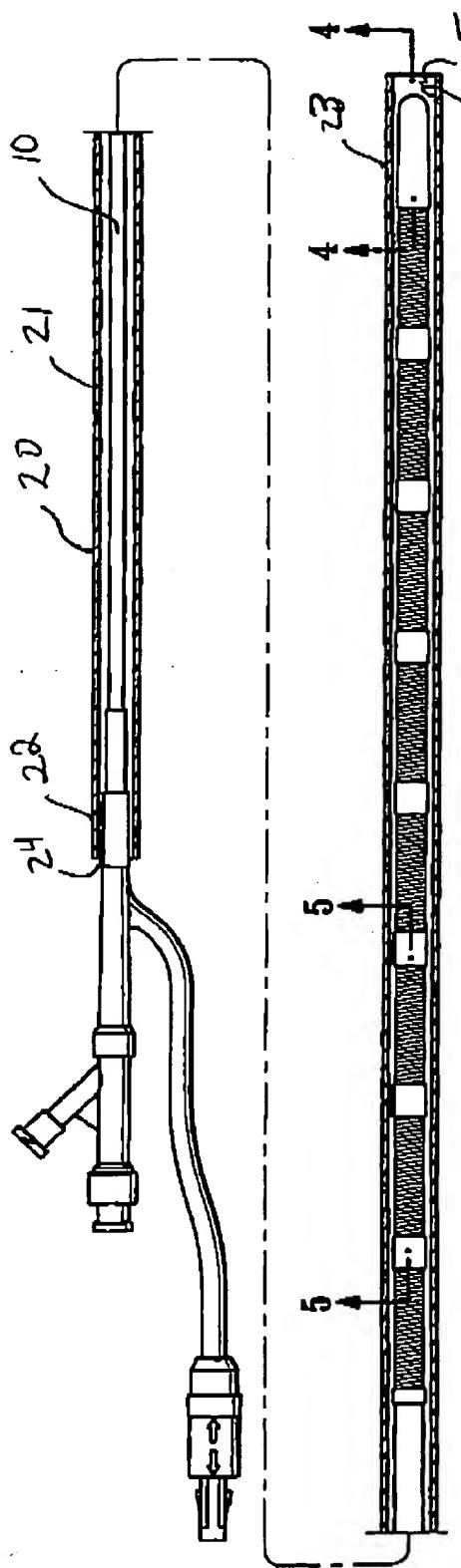


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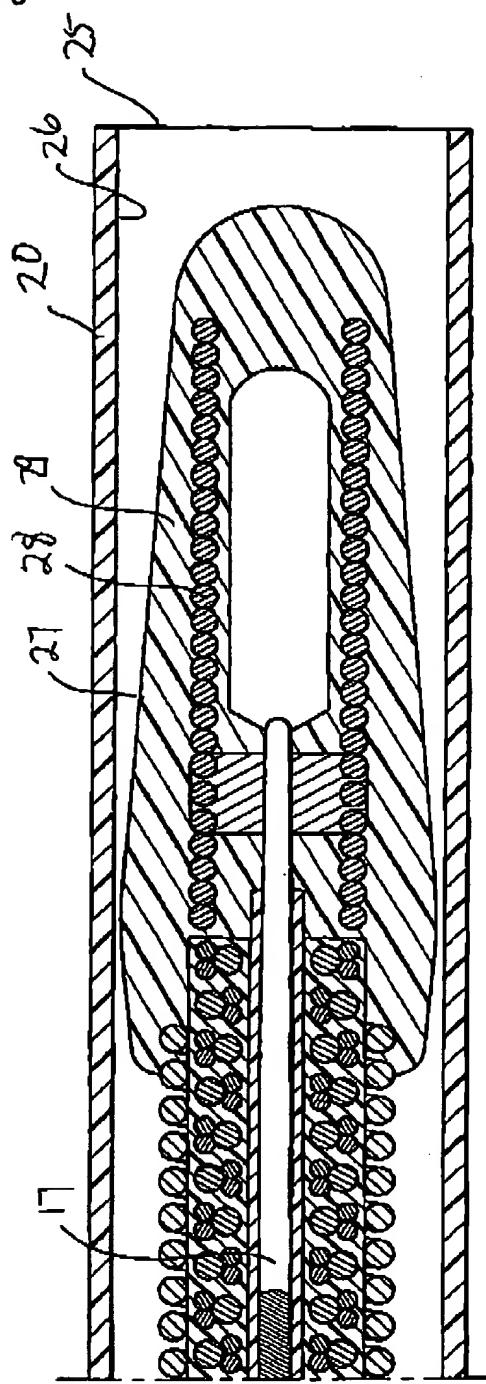
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FIG.



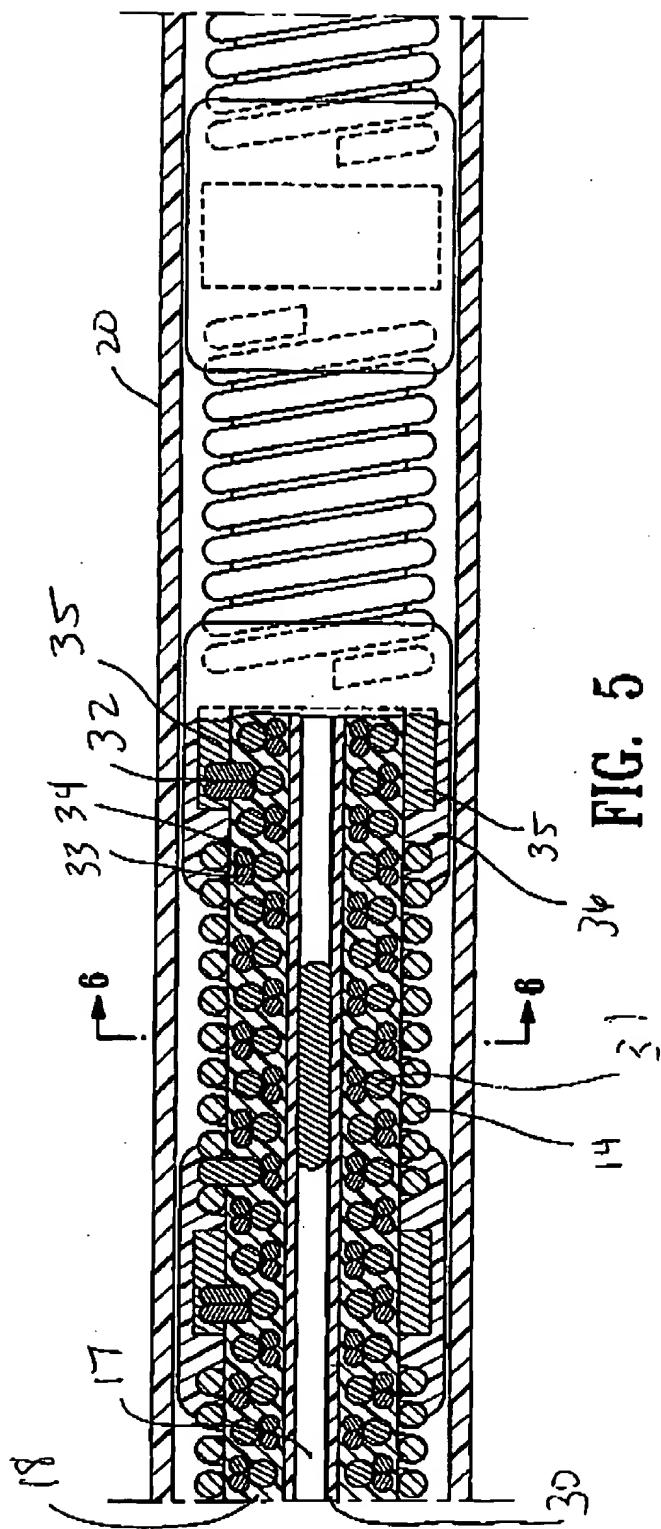
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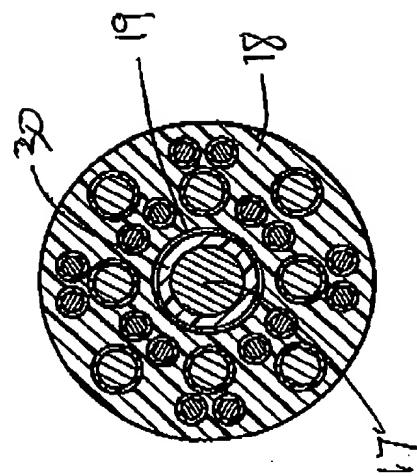


FIG. 7

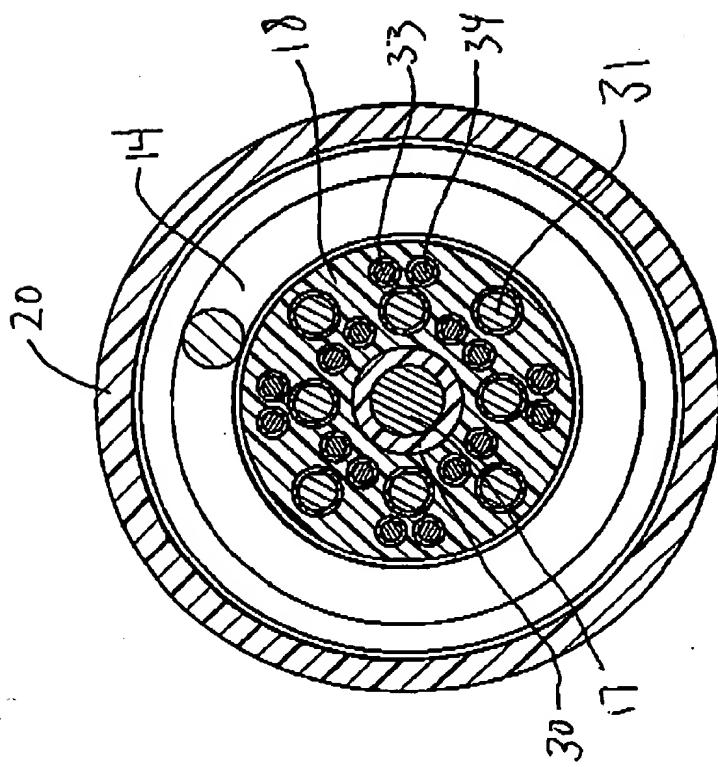


FIG. 6

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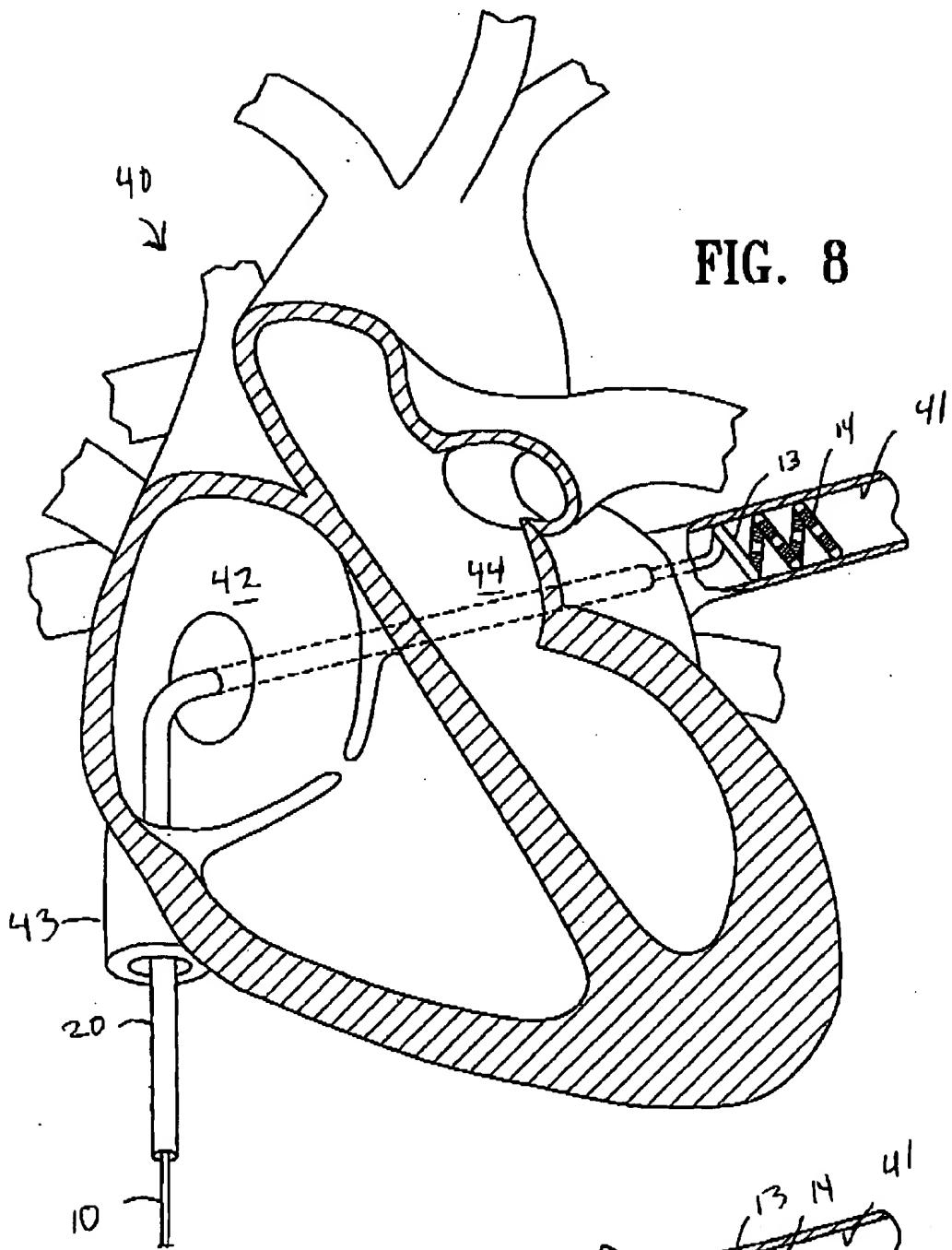


FIG. 9

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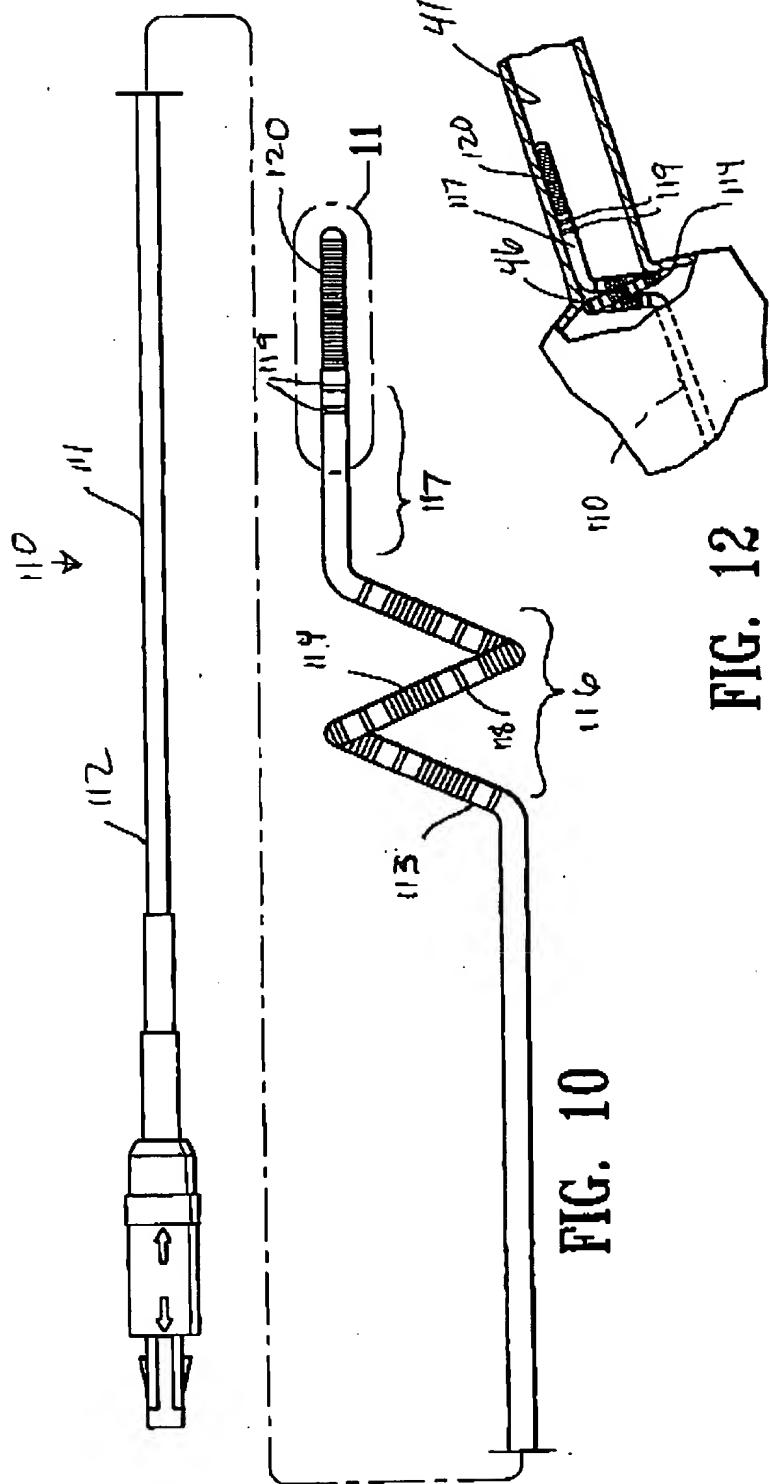
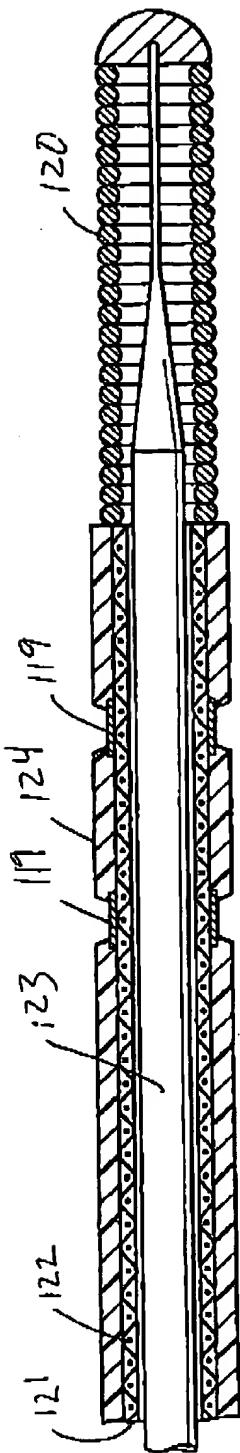


FIG. 12



11
11
FIG.

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April 19, 2001

Via Federal Express

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Our Ref.: 22963-1290

**Re: Draft U.S. Patent Application for
HELICALLY SHAPED ELECTROPHYSIOLOGY CATHETER**
Inventors: Hill et al.

Dear Dr. Chan:

Pursuant to your request I am forwarding another copy of the above-referenced draft application for review by the inventors. Each of the inventors should carefully review the draft and provide us with their comments. In addition, each of the inventors need to write-in their residence address and citizenship where indicated on the *Notice to Inventors When Reviewing this Draft Application*.

We will finalize the application once we have received comments on the draft. Should you have questions, please call.

Sincerely,

Nita J. Miller

Nita J. Miller
Patent Assistant

Enclosure

287093 v02.SV (65\\$1021.DOC)
4/19/01 12:37 PM (22963.1290)

From: HELLER EHRMAN WHITE & MCAULIFF (650)324-7000
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275 Middlefield Road
Menlo Park, CA, 94025



To: Eric Chan, Ph.D. (510)354-0176
Cardima, Inc.
47266 Benicia Street



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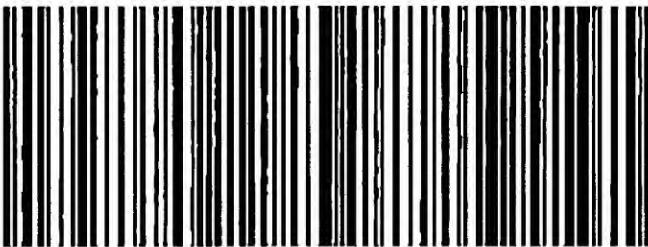
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Mark, Priscilla H.

From: Eric Chan [eric.chan@cardima.com]
Sent: Monday, April 23, 2001 5:19 PM
To: Priscilla Mark
Subject: Unipolar/Bipolar Usage

CONFIDENTIAL

RE: page 6 of patent application

Priscilla:

I am sending you some text to clarify electrode usage for the HELIX catheter. My handwritten notes are too messy perhaps. You will get a fedex package at Heller Ehrman by Wednesday AM. In it will be a current preferred embodiment drawing. I have also substituted Tim Huynh in place of Gabriel Vegh in the inventor list. ~ Thanks, Eric

"Preferably the electrodes on the helically shaped distal shaft section are configured by using a multiplexing switchbox for unipolar use during ablation, and bipolar use during sensing (mapping). The electrodes on the EP device shaft distal to the helical segment may be configured in a unipolar mode or bipolar mode for pacing and sensing. In the unipolar pacing/sensing mode, a separate, return electrode which is not on the EP device shaft but which is in contact with the exterior surface of the patient's body is used."

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sent e-mail to eric chan requesting inventor addresses, etc.

Plu 6/13/01